

Telephone: 1-888-888-3151

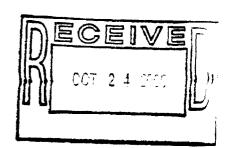
1-217-793-6443

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October 17, 2000

Mr. John B. Foret. Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labelling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
200 "C" Street S.W.
HFS-456
Washington, D.C. 20204



RE: Amendment on Master file document for MiracleHerb-GPTM

Dear Mr. Foret:

This is in response to your letter of October 10, 2000 regarding claims for the product MiracleHerb-GP™ pursuant to 21 U.S.C. 343(r)(6).

MiracleHerb-GP™ standardized gypenosides, which contains only natural ingredients, is not intended to be marketed as a drug or a product for treating, preventing, curing or mitigating diseases. After carefully reviewing your comments, the following changes will be taken effect on all future labels associated with MiracleHerb-GP™:

- 1. The following claims will be eliminated:
  - -Maintain normal cholesterol and triglycerids levels
  - -Maintain a healthy blood pressure
  - -Decrease vascular resistance and increase coronary blood flow
  - -Reduce vascular plaque
- 2. The claim "maintain immunocompetence" will be changed to "promote healthy immune functions".
- 3. The claim "maintain normal blood glucose level" will be changed to "maintain normal glucose metabolism".

We believe that the amended structure/function claims, which are supported by published peer reviewed scientific literatures, meet the requirements as stipulated in 21 U.S.C.

915-016 2

Also see docket 975-0163

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343(r)(6). The manufacturer is dedicated to bring superior natural products to the market in compliance with all FDA regulations on dietary supplements.

The manufacture requests that this amended information together with the information previously submitted be entered into an FDA master file for reference.

Thank you very much for your consideration. The master file number can be sent to my attention at the address listed above.

Sincerely,

Lin Yan

Scientific and Regulatory Affairs